



U.S. Department  
of Transportation

Pipeline and  
Hazardous Materials  
Safety Administration

COMPETENT AUTHORITY CERTIFICATION  
FOR A TYPE B(U)  
RADIOACTIVE MATERIALS PACKAGE DESIGN  
CERTIFICATE USA/0562/B(U)-96, REVISION 7

East Building, PHH-23  
1200 New Jersey Avenue SE  
Washington, D.C. 20590

REVALIDATION OF SOUTH AFRICAN COMPETENT AUTHORITY  
CERTIFICATE ZA/NNR 1005/B(U)-96

This certifies that the radioactive material package design described is hereby approved for use within the United States for import and export shipments only. Shipments must be made in accordance with the applicable regulations of the International Atomic Energy Agency<sup>1</sup> and the United States of America<sup>2</sup>.

1. Package Identification - ZA/NNR1005/B(U)-96 (Beatrice).
2. Package Description and Authorized Radioactive Contents - as described in South Africa Certificate of Competent Authority ZA/NNR 1005/B(U)-96, Revision 01 (attached).
3. General Conditions -
  - a. Each user of this certificate must have in his possession a copy of this certificate and all documents necessary to properly prepare the package for transportation. The user shall prepare the package for shipment in accordance with the documentation and applicable regulations.
  - b. Each user of this certificate, other than the original petitioner, shall register his identity in writing to the Office of Hazardous Materials Technology, (PHH-23), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington D.C. 20590-0001.
  - c. This certificate does not relieve any consignor or carrier from compliance with any requirement of the Government of any country through or into which the package is to be transported.

---

<sup>1</sup> "Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), No. TS-R-1 (ST-1, Revised)," published by the International Atomic Energy Agency(IAEA), Vienna, Austria.

<sup>2</sup> Title 49, Code of Federal Regulations, Parts 100-199, United States of America.

**CERTIFICATE USA/0562/B(U)-96, REVISION 7**

- d. Records of Quality Assurance activities required by Paragraph 310 of the IAEA regulations<sup>1</sup> shall be maintained and made available to the authorized officials for at least three years after the last shipment authorized by this certificate. Consignors in the United States exporting shipments under this certificate shall satisfy the applicable requirements of Subpart H of 10 CFR 71.
4. Special Conditions -
  - a. Prior to each shipment, the inner cavity liner, including the cavity liner welds, must be visually inspected to assure that there is no visible evidence of cracks, pinholes or other defects.
  - b. In accordance with the attached South African certificate, this certificate cannot be used until January 2, 2009.
5. Marking and Labeling - The package shall bear the marking USA/0562/B(U)-96 in addition to other required markings and labeling.
6. Expiration Date - This certificate expires on January 02, 2013. On January 02, 2009, this certificate supersedes all previous revisions of USA/0562/B(U)-96.

This certificate is issued in accordance with paragraph 808 of the IAEA Regulations and Section 173.473 of Title 49 of the Code of Federal Regulations, in response to the May 14, 2008 petition by NTP Radioisotopes, Pretoria, South Africa, South Africa, and in consideration of other information on file in this Office.

Certified By:



Robert A. Richard  
Deputy Associate Administrator for Hazardous Materials Safety

**Sep 18 2008**  
(DATE)

Revision 7 - issued to revalidate South Africa Certificate of Competent Authority ZA/NNR1005/B(U)-96 Revision 01, dated May 13, 2008.



**CERTIFICATE NO. ZA/NNR/1005/B(U) – 96**

**REVISION 01**

**PACKAGE DESIGN APPROVAL**

This is to certify that the National Nuclear Regulator, being, for the purpose of the International Atomic Energy Agency, the Competent Authority in the Republic of South Africa in respect of the transport of radioactive material, has Re-Certified the Certificate of Approval of the Package Design, as described herein, and which is intended to contain the authorised radioactive materials described herein, as having met the regulatory requirements for Type B(U) packages as described in the International Atomic Energy Agency Safety Standards Series No. TS-R-1, Regulations for the Safe Transport of Radioactive Material, 2005 Edition, Vienna 2005.

**1. CERTIFICATE**

Effective Date : 2 January 2009  
Expiry Date : 2 January 2013

**2. COMPETENT AUTHORITY**

National Nuclear Regulator  
P O Box 7106  
Centurion  
0046  
South Africa

**3. THIS CERTIFICATE IS ISSUED ON THE BASIS OF THE APPLICATION  
SUBMITTED BY**

**Name and Address of Applicant:**

South African Nuclear Energy Corporation  
P O Box 582  
Pretoria  
0001  
South Africa

MTM

#### 4. TITLE AND IDENTIFICATION OF REPORTS

- Document No. NTP-SAR-0002 Rev (0): Safety Analysis Report: "Beatrice" Transport Package: ZA/NNR 1005/B(U)-96
- Drawing I:E 144:000 Rev M
- Licencing Submission NAR 0091: Safety Analysis Report: "Beatrice" Transport Package ZA/NNR 1005/B(U)-96

#### 5. PACKAGE IDENTIFICATION

Model Number: ZA/NNR/1005/B(U) – 96

#### 6. PACKAGE DESCRIPTION

The Package Assembly (See Figure 1) consists of a Stainless Steel Inner Container, which is placed inside a Stainless Steel Outer Casing. The Stainless Steel Inner Container is sealed by two "O"-rings that serve as outer containment barrier. Solid depleted uranium is used to provide shielding in the Inner Container. A Cork Liner, situated between the Inner Container and the Outer Casing, serves as a thermal protective envelope during a fire and also serves to cushion the internals from mechanical shocks.

A cavity inside the Inner Container Shield contains an Inner Product Container fitted with an "O"-ring, which serves as the primary containment for this package and houses the product bottle. The transport package schematic is detailed in Figure 2.

#### 7. AUTHORISED CONTENTS

| Radionuclide      | Activity               | Physical state | Chemical state   | Product Bottle         | Use         |
|-------------------|------------------------|----------------|--|------------------------|-------------|
| <sup>99</sup> Mo  | 1500 Ci<br>(55.50 TBq) | Solid          | MoO <sub>3</sub> powder  | Stainless Steel/ Glass | Medical     |
|                   | 1500 Ci<br>(55.50 TBq) | Liquid         | NaOH solution  | Stainless Steel        |             |
|                   | 320 Ci<br>(11.84 TBq)  | Liquid         | NaOH solution stabilised with NH <sub>4</sub> NO <sub>3</sub>                    | Stainless Steel        |             |
|                   | 660 Ci<br>(24.42 TBq)  | Liquid         | NaOH solution stabilised with NaOCl  | Stainless Steel        |             |
|                   | 900 Ci<br>(33.30 TBq)  | Liquid         | NaOH solution stabilised with NaNO <sub>3</sub> or H <sub>2</sub> O <sub>2</sub> | Stainless Steel        |             |
| <sup>131</sup> I  | 250 Ci<br>(9.25 TBq)   | Liquid         | NaOH solution with or without reducing agent                                     | Glass                  | Medical     |
| <sup>192</sup> Ir | 4000 Ci<br>(148.0 TBq) | Solid          | Ir-metal   | Stainless Steel        | Radiography |

## **8. CONDITIONS FOR USE OF THE PACKAGING**

The maintenance required on this transport package is described in the handling instructions. NTP-WPD-9003: Handling Instructions for the ZA/NNR 1005/B(U)-96 "Beatrice" Transport Package and in essence entails the following:

- 8.1 The on-condition replacement of the "O"-rings of the Inner Container.
- 8.2 Replacement of "O"-ring of the Inner Product Container before every shipment of radioactive material.
- 8.3 Replacement of the Inner Product Container after every shipment of liquid I-131 if any leakage from the product bottle into the Inner Product Container has occurred or is suspected.
- 8.4 The cleaning of the outside surfaces, especially the identification plate of all old labels.
- 8.5 The coating of all screws with copper grease before every shipment to prevent galling.
- 8.6 The pressure testing of the Inner Product Container every 3 years.

## **9. NOTIFICATION**

- 9.1 The owner of a package, manufactured in accordance to the design covered by this Certificate, shall forward the packaging serial number to the competent authority.
- 9.2 Should a package be disposed of or change ownership, then this change must be notified to the competent authorities.
- 9.3 Accordingly, the party relinquishing ownership of a package shall forward the name of the new owner to the competent authority.
- 9.4 The consignor of a package compliant with the design covered by this Certificate, shall check that the package bears a serial number, as well as a Model Number, as identified in 5 above.

## **10. MODE(S) OF TRANSPORT**

The package described by this Certificate may be transported by all modes of transport.

## **11. SPECIFICATIONS OF QUALITY ASSURANCE PROGRAMME**

- 11.1 A quality assurance system as described in document NTP-PRG-0100 must be applied to the design, manufacture, controls and tests of the packaging.

11.2 A quality plan and design report for the inner product container report NTP-VLG-03/83 must be applied

11.3 All packaging must be periodically inspected and as necessary, repaired and maintained in good condition so that they continue to comply with the relevant requirements and specifications, even after repeated use.

## **12. GENERAL CONDITIONS**

12.1 Each user of this certificate must have in his possession a copy of this certificate and all documents necessary to properly prepare the package for transportation.

12.2 This certificate does not relieve the consignor or carrier from the compliance with any requirements of the government of any country through or into which the package will be transported.

## **13. MARKING AND LABELS**

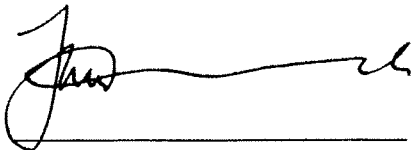
The package must bear the marking "ZA/NNR/1005/B(U) – 96" in addition to any other required markings and labelling.

## **14. RELEVANT REGULATIONS**

International Atomic Energy Agency Safety Standards Series No. TS-R-1, Regulations for the Safe Transport of Radioactive Material, 2005 Edition, Vienna, 2005.

## **15. EXPIRY DATE**

This certificate expires at midnight on 02 January 2013.



**M. MAGUGUMELA**  
**CHIEF EXECUTIVE OFFICER**

13 / 05 / 08

**DATE:**

National Nuclear Regulator  
P O Box 7106  
CENTURION  
OO46

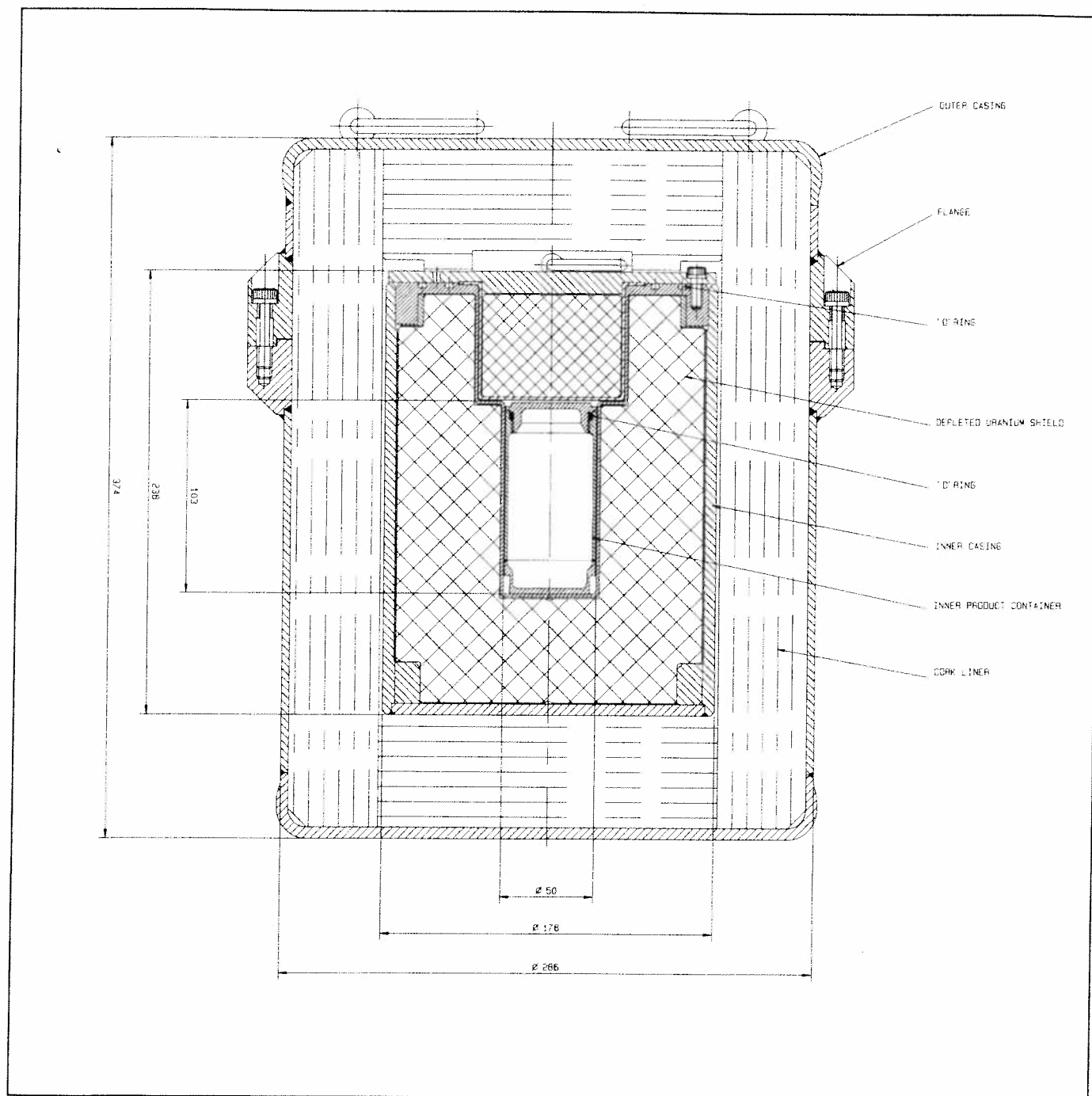
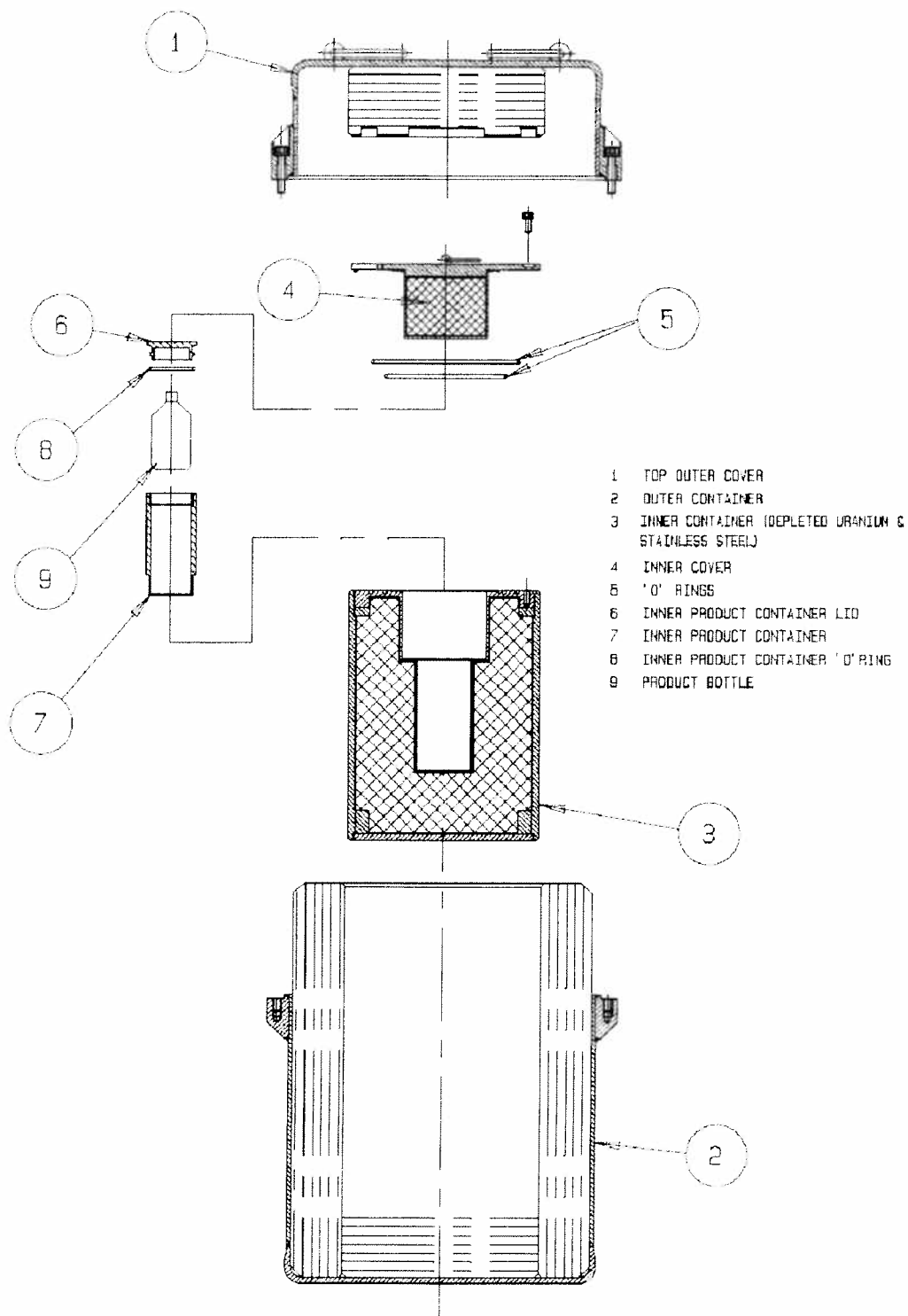


Figure 1: Beatrice Package Outline Drawing

M TM



**Figure 2: Schematic of Beatrice Package**





U.S. Department  
of Transportation

Pipeline and  
Hazardous Materials  
Safety Administration

East Building, PHH-23  
1200 New Jersey Avenue SE  
Washington, D.C. 20590

**CERTIFICATE NUMBER:** USA/0562/B(U)-96, Revision 7

**ORIGINAL REGISTRANT(S):**

Mr. H.G. Wortmann  
Manager: Quality, Regulatory and Safety  
NTP Radioisotopes  
P.O. Box 582  
Pretoria 0001, South Africa  
South Africa

**REGISTERED USER(S):**

Ms. April Chance  
Manager, Radiological Affairs  
Mallinckrodt Inc.  
675 McDonnell Blvd  
Hazelwood, 63042  
USA

Henk Doornebos  
Manager Distribution  
Mallinckrodt Medical BV  
Westerduinweg 3  
PO Box 3  
1755 ZG  
Petten,  
The Netherlands

Mr. B. David  
Head, Radiochemistry Department  
IRE  
Avenue de l'Esperance, 1  
B-6220  
Fleurus,  
Belgium